UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2022

Gamida Cell Ltd.
(Exact name of registrant as specified in its Charter)

Israel	001-38716	Not Applicable
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

5 Nahum Heftsadie Street Givaat Shaul, Jerusalem Israel	91340
(Address of principal executive offices)	(Zip Code)

+972 (2) 659-5666
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, NIS 0.01 par value	GMDA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, Gamida Cell Ltd. (the "***Company***") issued a press release announcing the Company's financial results for the quarter ended March 31, 2022. In addition to disclosing results that are determined in accordance with Generally Accepted Accounting Principles (GAAP), the Company also discloses non-GAAP results of operations, which are adjusted from GAAP to exclude non-cash compensation related to stock awards. The Company is presenting non-GAAP information excluding non-cash compensation related to stock awards because the Company believes it is useful for investors in assessing the Company's operating results. A copy of the release is furnished with this report as an exhibit pursuant to "Item 2.02. Results of Operations and Financial Condition" of Form 8-K in accordance with SEC Release Nos. 33-8216 and 34-47583.

The information in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "***Exchange Act***") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated May 10, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Gamida Cell Ltd.

Dated: May 10, 2022

By: /s/ Shai Lankry
Shai Lankry
Chief Financial Officer

Exhibit 99.1

Gamida Cell Reports First Quarter 2022 Financial Results and Provides Company Update

- On track for full BLA submission of omidubicel in the second quarter of 2022 -

- Planning to open sites for enrollment in second quarter of 2022 for Phase 1/2 study of GDA-201 in patients with follicular and diffuse large B-cell lymphomas -

- Presented new preclinical data supporting potential of NAM-enabled, genetically modified NK pipeline cell therapy candidates GDA-301 and GDA-601 -

- Finished first quarter of 2022 with approximately $70 million in cash; sufficient cash to fund the company's operations into mid-2023 -

- Company to host conference call at 8:00 a.m. ET today -

Boston, Mass. – May 10, 2022 – Gamida Cell Ltd. (Nasdaq: GMDA), the leader in the development of NAM-enabled cell therapies for patients with hematologic and solid cancers and other serious diseases, today provided a business update and reported financial results for the quarter ended March 31, 2022. Net loss for the first quarter of 2022 was $20.2 million, compared to a net loss of $19.2 million in the first quarter of 2021. As of March 31, 2022, Gamida Cell had total cash and cash equivalents of $69.7 million.

During the past quarter, Gamida Cell:

- Progressed omidubicel, a potentially life-saving cell therapy candidate for patients with blood cancers in need of stem cell transplant, towards full Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) in the second quarter of this year.

- Planning to open sites for enrollment in second quarter of 2022 for Phase 1/2 study of lead natural killer (NK) cell therapy candidate, GDA-201, for patients with follicular and diffuse large B-cell lymphomas. The FDA recently cleared the company's Investigational New Drug (IND) application and removed the clinical hold on the program, allowing Gamida Cell to move forward with the planned Phase 1/2 study with the cryopreserved formulation.

- Continued development of the company's NAM-enabled NK cell pipeline, including genetically modified product candidates GDA-301, GDA-401, GDA-501 and GDA-601, which focus on solid-tumor and hematological cancers. These product candidates utilize CAR, membrane bound- and CRISPR-mediated technologies to increase the NK cell targeting, potency and persistence against hematologic malignancies and solid tumors.

"We have made significant strides advancing our pipeline and demonstrating the potential benefit of our NAM-enabled cell therapy candidates for patients with blood cancers and other serious blood," said Julian Adams, Ph.D., chief executive officer of Gamida Cell. "And this starts with the recent milestone of the clearance of our IND for the cryopreserved formulation of GDA-201 by removal of the clinical hold. We are proceeding with operational activities in second quarter at multiple sites for our planned Phase 1/2 study, and are on track to advance this novel cell therapy candidate to the clinic this year. We were also pleased to present important data on omidubicel, supporting its potential long term clinical benefit, as we approach the full BLA submission for omidubicel during the second quarter of this year."

First Quarter and Recent Developments

Omidubicel: Advanced Cell Therapy

- **BLA submission:** Following the receipt of positive Type B meeting correspondence from the FDA confirming that analytical comparability has been established between product made at Gamida Cell's wholly-owned commercial manufacturing facility and the product that was manufactured for the Phase 3 study, Gamida Cell initiated a rolling BLA submission for omidubicel in February 2022. The company is on-track to complete the BLA submission in the second quarter of 2022. In parallel with the BLA submission, Gamida Cell is assessing alternatives for the commercialization of omidubicel, including potential U.S. or global partnerships.

- **New data presented at the 2022 Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR Tandem Meetings (TCT):** In April 2022, Gamida Cell announced two oral and six poster presentations that focused on omidubicel's positive Phase 3 clinical data, Gamida Cell's health economic efforts, and transcriptional and metabolic profiling for our lead NK candidate, GDA-201. These presentations continued to add to the totality of evidence supporting omidubicel as a potential allogeneic hematopoietic stem cell transplant and our developments with our NK candidates. Highlights from these presentations included:

    - A presentation which received TCT's Best Abstract Award entitled "Hematopoietic Stem Cell Transplantation (HSCT) with Omidubicel is Associated with Enhanced Circulatory Plasmacytoid Dendritic Cells (pDC), NK Cells and CD4+ T Cells with Lower Rates of Severe Infections Compared to Standard Umbilical Cord Blood Transplantation." This presentation detailed that Allo-HSCT with omidubicel demonstrated rapid hematopoietic recovery, reduced rates of infections and no increase in acute or chronic GvHD rates compared with standard UCB, with no unexpected adverse events attributable to ex vivo expansion.

    - An oral presentation titled "Allogeneic Hematopoietic Stem Cell (allo-HSCT) Transplant with Omidubicel Demonstrates Sustained Clinical Improvement Versus Standard Myeloablative Umbilical Cord Blood Transplantation (UCBT): Final Results of a Phase III Randomized, Multicenter Study." The data showed that the advantages of early engraftment and lower infections with omidubicel translated into long term clinical benefits in the first-year post-transplant, as demonstrated by reduction in non-relapse mortality, and no increase in relapse or GvHD rate compared to Umbilical Cord Blood Transplantation (UCBT). Additionally, there was a continued trend toward improved OS in favor of the omidubicel arm over time (73% vs 60%).

    - A health economic study titled "Projected Impact of Omidubicel on Racial and Ethnic Disparities in Allogeneic Hematopoietic Cell Transplant (allo-HCT) Access and Outcomes for Patients with Hematologic Malignancies in the US." The study, which assessed the projected impact of omidubicel on racial and ethnic health disparities in a projection model, showed that, if approved, broad access to omidubicel was projected to decrease time to allo-HCT and improve allo-HCT outcomes overall, with the greatest improvements among racial and ethnic groups least served by current graft sources.

GDA-201: NAM-Enabled NK Cell Therapy

- **IND cleared and clinical hold removed for Phase 1/2 Study with cryopreserved formulation of GDA-201:** Gamida Cell recently announced that FDA cleared its IND application and removed the clinical hold for a cryopreserved formulation of GDA-201. The company is now proceeding with operational activities at several clinical trial sites, and is on track to initiate a company-sponsored Phase 1/2 clinical study in patients with follicular and diffuse large B-cell lymphomas in 2022.

NAM-Enabled NK Cell Pipeline Expansion

- **Progressed NAM-enabled genetically modified NK pipeline:** Gamida Cell continues to progress its NAM-enabled genetically modified NK pipeline, which utilizes CAR, membrane bound- and CRISPR-mediated technologies to increase targeting, potency and persistence against hematologic malignancies and solid tumors. The company plans to conduct preclinical proof of concept studies for these genetically modified NK therapeutic targets and to select a product candidate for IND enabling studies by the end of 2022. These therapeutic targets include:

    - GDA-301: Knockout of CISH (cytokine inducible SH2 containing protein) in NK cells using CRISPR/Cas9 in combination with a membrane-bound IL-15/IL-15Ra;

    - GDA-401: A development candidate with an undisclosed target.

    - GDA-501: Anti HER2 CAR-engineered NK cells to target solid tumors expressing HER2, based on a single-chain variable fragment of the widely used humanized monoclonal antibody trastuzumab; and

    - GDA-601: CRISPR Knockout of CD38 on NK cells combined with anti CD38 CAR. CD38 is an established immunotherapeutic target in multiple myeloma, but its expression on NK cells and its further induction during ex vivo NK cell expansion represents a barrier to the development of an anti CD38 CAR-NK cell therapy. Gamida Cell is advancing this program in collaboration with the Dana-Farber Cancer Institute to study the in vitro cytotoxicity of GDA-601 in fresh samples from multiple myeloma patients.

- **Presented preclinical data from product candidates at the International Society for Cell & Gene Therapy (ISCT) 2022**: Gamida Cell recently presented new preclinical data for GDA-301 and GDA-601 that continued to demonstrate the potential of these product candidates:

    - A poster titled “GDA-301: Engineered NAM-NK Cells via CISH Knockout and Membrane-Bound IL-15 Expression Increases Cytotoxicity Against Malignancies,” detailed that GDA-301 produces enhanced potency and persistence with combined genetic manipulation of CISH gene editing and the engineered expression of membrane-bound IL-15 for targeting hematologic malignancies and solid tumors.

    - In a poster titled “GDA-601: NAM-NK Cells With CD38 Knockout Expresses Enhanced CD38 Chimeric Antigen Receptor and Targets Multiple Myeloma Cells With Increased Cytotoxicity,” it was shown that GDA-601 displays superior antitumoral responses against multiple myeloma cells and represents a promising adoptive cell therapeutic strategy.

First Quarter 2022 Financial Results

- Research and development expenses were $11.3 million in the first quarter of 2022, compared to $11.4 million in the same quarter in 2021. The decrease was primarily due to a $1.1 million decrease in omidubicel and GDA 201 clinical study activities, offset by an increase of $1.0 million in broadening the company’s scientific capabilities and talent.

- Commercial expenses were $3.9 million in the first quarter of 2022, compared to $4.2 million in the first quarter of 2021. The decrease was attributable mainly to reducing the company’s near-term commercial readiness expenses, as it is assessing alternatives for the commercialization of omidubicel, including potential U.S. or global partnerships.

- General and administrative expenses were $4.1 million in the first quarter of 2022, compared to $3.5 million in the same period in 2021. The increase was mainly due to a $0.5 million increase in headcount and related expenses.

- Finance expenses, net, were $0.9 million in the first quarter of 2022, compared to $0.1 million in the same period in 2021. The increase was primarily due to a $0.6 million increase in interest expenses from convertible notes.

- Net loss was $20.2 million in the first quarter of 2022, compared to a net loss of $19.2 million in the first quarter of 2021.

2022 Financial Guidance

Gamida Cell expects that its current cash and cash equivalents will support the company's ongoing operating activities into mid 2023. This cash runaway guidance is based on the company's current operational plans and excludes any additional funding and any business development activities that may be undertaken.

Expected Milestones in 2022

Omidubicel

- Completion of full BLA submission to the FDA in the second quarter of 2022

GDA-201

- Initiation of a company-sponsored Phase 1/2 clinical study with the cryopreserved formulation in follicular and diffuse large B-cell lymphomas

NK cell pipeline expansion

- Conduct preclinical proof of concept studies of the NAM-enabled, genetically modified NK therapeutic targets
- Select pipeline candidate for IND-enabling studies

Conference Call Information

Gamida Cell will host a conference call today, May 10, 2022, at 8:00 a.m. ET to discuss these financial results and company updates. A live webcast of the conference call can be accessed in the "Investors & Media" section of Gamida Cell's website at www.gamida-cell.com. To participate in the live call, please dial 866-930-5560 (domestic) or 409-216-0605 (international) and refer to conference ID number 3344029. A replay of the webcast will be available approximately two hours after the event, for approximately 30 days.

About Omidubicel

Omidubicel is an advanced cell therapy candidate under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with blood cancers. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the U.S. FDA and has also received Orphan Drug Designation in the U.S. and EU. Gamida Cell has completed an international, multi-center, randomized Phase 3 study (NCT0273029) evaluating the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing allogeneic bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. That study achieved its primary endpoint, demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in a patient's recovery from a stem cell transplant. The Phase 3 study also achieved its secondary endpoints of reduced time to platelet engraftment, reduced infections and fewer days of hospitalization. Gamida Cell initiated a rolling BLA submission for omidubicel in the first quarter of 2022 with full BLA submission on track for the second quarter of 2022. In 2019, approximately 8,000 patients who were 12 years old and up with hematologic malignancies underwent an allogeneic stem cell transplant. Unfortunately it is estimated that another 1,200 patients were eligible for transplant but could not find a donor source. Omidubicel has the opportunity, upon FDA approval to improve outcomes for patients based on transplanter feedback and increase access for patients to get to transplant. Omidubicel has the potential to treat approximately 2000 – 2500 patients each year in the U.S. For more information about omidubicel, please visit https://www.gamida-cell.com.

Omidubicel is an investigational therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

About GDA-201

Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy candidate for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201, the lead candidate in the NAM-enabled NK cell pipeline, has demonstrated promising initial clinical trial results. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation in the bone marrow and lymphoid organs. Furthermore, GDA-201 improves antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. There are approximately 40,000 patients with relapsed/refractory lymphoma in the E.U.5 and U.S. which is the patient population that will be studied in the GDA-201 Phase 1/2 clinical trial

For more information about GDA-201, please visit https://www.gamida-cell.com. For more information on the Phase 1/2 clinical trial of GDA-201, please visit www.clinicaltrials.gov.

GDA-201 is an investigational therapy, and its safety and efficacy have not been established by the FDA or any other health authority.

About NAM Technology

Our NAM-enabling technology, supported by positive Phase 3 data, is designed to enhance the number and functionality of targeted cells, enabling us to pursue a curative approach that moves beyond what is possible with existing therapies. Leveraging the unique properties of NAM (Nicotinamide), we can expand and metabolically modulate multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' active phenotype and enhance potency. Additionally, our NAM technology improves the metabolic fitness of cells, allowing for continued activity throughout the expansion process.

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapies for patients with solid tumor and blood cancers and other serious blood diseases. We apply a proprietary expansion platform leveraging the properties of NAM to allogeneic cell sources including umbilical cord blood-derived cells and NK cells to create therapies with potential to redefine standards of care. These include omidubicel, an investigational product with potential as a life-saving alternative for patients in need of bone marrow transplant, and a line of modified and unmodified NAM-enabled NK cells targeted at solid tumor and hematological malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, Twitter, Facebook or Instagram at @GamidaCellTx.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to timing of initiation and progress of, and data reported from, the clinical trials of Gamida Cell's product candidates (including GDA-201), anticipated regulatory filings (including the timing of submission of the BLA for omidubicel to the FDA), commercialization planning efforts, and the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including GDA-201 and omidubicel), and Gamida Cell's expectations for the expected clinical development milestones set forth herein. Any statement describing Gamida Cell's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to a number of risks, uncertainties and assumptions, including those related to the impact that the COVID-19 pandemic could have on our business, and including the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; clinical, scientific, regulatory and technical developments; and those inherent in the process of developing and commercializing product candidates that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such product candidates. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section and other sections of Gamida Cell's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (SEC) on March 24, 2022, as amended, and other filings that Gamida Cell makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Although Gamida Cell's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Gamida Cell. As a result, you are cautioned not to rely on these forward-looking statements.

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CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

U.S. dollars in thousands (except share and per share data)

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 42,057	$ 55,892
Marketable securities	27,661	40,034
Prepaid expenses and other current assets	2,994	2,688
Total current assets	72,712	98,614
NON-CURRENT ASSETS:		
Restricted deposits	3,893	3,961
Property, plant and equipment, net	37,533	35,180
Operating lease right-of-use assets	6,722	7,236
Severance pay fund	2,046	2,148
Other long-term assets	1,632	1,647
Total non-current assets	51,826	50,172
Total assets	$ 124,538	$ 148,786

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

U.S. dollars in thousands (except share and per share data)

	March 31, 2022	December 31, 2021
LIABILITIES AND SHARHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 4,346	$ 8,272
Employees and payroll accruals	4,119	4,957
Operating lease liabilities	2,596	2,699
Accrued interest of convertible senior notes	551	1,640
Accrued expenses and other current liabilities	8,866	7,865
Total current liabilities	20,478	25,433
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	71,607	71,417
Accrued severance pay	2,327	2,396
Long-term operating lease liabilities	5,142	5,603
Total non-current liabilities	79,076	79,416
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Share capital -	169	169
	*	-
Additional paid-in capital	382,495	381,225
Accumulated deficit	(357,680)	(337,457)
Total shareholders' equity	24,984	43,937
Total liabilities and shareholders' equity	$ 124,538	$ 148,786

* Represents an amount lower than $1.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

U.S. dollars in thousands (except share and per share data)

	Three months ended March 31,	
	2022	**2021**
Research and development expenses, net	$ 11,305	$ 11,360
Commercial expenses	3,879	4,231
General and administrative expenses	4,139	3,513
Total operating loss	19,323	19,104
Financial expenses, net	900	82
Loss	20,223	19,186
Net loss per share attributable to ordinary shareholders, basic and diluted	$ 0.34	$ 0.32
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	59,474,366	59,122,973

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

U.S. dollars in thousands (except share and per share data)

	Three months ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Loss	$ (20,223)	$ (19,186)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	112	98
Financing expense (income), net	(1,172)	220
Share-based compensation	1,194	913
Amortization of issuance costs	191	323
Operating lease right-of-use assets	562	516
Operating lease liabilities	(613)	(929)
Accrued severance pay, net	33	-
Increase in prepaid expenses and other assets	(889)	(515)
Increase (decrease) in trade payables	(3,927)	907
Decrease in accrued expenses and current liabilities	(996)	(3,192)
Net cash used in operating activities	(25,728)	(20,845)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(723)	(2,806)
Purchase of marketable securities	(2,086)	-
Proceeds from maturity of marketable securities	14,126	-
Proceeds from restricted deposits	500	-
Net cash provided by (used in) investing activities	$ 11,817	$ (2,806)
Cash flows from financing activities:		
Proceeds from exercise of options	76	502
Proceeds from issuance of convertible senior notes, net	-	70,777
Net cash provided by financing activities	76	71,279
Increase (decrease) in cash and cash equivalents	(13,835)	47,628
Cash and cash equivalents at beginning of period	55,892	127,170
Cash and cash equivalents at end of period	$ 42,057	$ 174,798